# Plan Overview

*A Data Management Plan created using DMPTool*

**Title:** Carreadores lipídicos nanoestruturados para coencapsulação e liberação sustentada de fenretinida e álcool perílico no tecido mamário visando à prevenção do desenvolvimento e recorrências de câncer de mama

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**Template:** USP Template - Minimum

**Project abstract:**

Chemoprevention is an important strategy for breast cancer prevention in women with high risk of developing this disease. However, the strategies currently available provoke severe adverse effects, like fatigue, reduction of bone density, thromboembolism, cardiovascular symptoms and increased risk of developing other tumors, which constitute an important factor for low adherence of the high risk population to preventive therapies. We have previously developed nanostructured lipid carriers (NLC) for fenretinide and perillyl alcohol (POH) release in the mammary tissue as a new strategy for breast cancer chemoprevention. We now propose to expand the characterization and biological evaluation of the developed nanocarriers. Effects of the association between distinct concentrations of the active compounds on the NLC characteristics, its ability to prolong the *in vitro* release and its cellular effects on T-47D, MCF-7, MDA-MB-231 and MCF-10A cell lines will be evaluated through cytotoxicity, cytostaticity and invasion studies. After optimization of the nanocarrier, cellular uptake and *in vitro* tumor penetration will be assessed. Spreading of the formulation in tissue will be estimated by two methods, using hydroxypropyl cellulose and porcine ear skin. An animal model of induced carcinogenesis, added to hystological analysis, will be used to study the distribution of the compounds *in vivo* and promote minimal systemic exposure associated to efficacy in preventing breast tumors.

**Start date:** 01-27-2022

**End date:** 01-27-2027

**Last modified:** 01-23-2024

relationship to, your project or proposal

## Carreadores lipídicos nanoestruturados para coencapsulação e liberação sustentada de fenretinida e álcool perílico no tecido mamário visando à prevenção do desenvolvimento e recorrências de câncer de mama - Description of Data and Metadata produced by the project

Data created by this project include:

- optical and electron microscopy images of nanocarriers and histology images, which will be kept as tiff files

- data on physicochemical characterization and stability of nanocarriers (size, charge, viscosity): these data will be kept as generated in the Malvern software and as .pdf files to enable visualization in other computers.

- colorimetric data on cell growth and survival, colorimetric data on cellular production of reactive oxigen species, flow cytometry data, HPLC data: will be kept as Excel files. This type of file is easy for data export from equipment (such as plate readers) software, and readable in most computers. Chromatograms will be kept as generated in the Shimadzu CLASS VP software

- animal-related records such as changes on weight and tumor development based on treatment will be kept in laboratory notebooks and folders labeled with the protocol number and dates.

Folders and files be structured and named according to the assay and date.

- Microscopy images (from histological analysis, optical and electron microscopy images of cells and spheroids, fluorescence images of cells) will be kept as tiff files.
- Size distribution and zeta potential data will be kept as generated in the Malvern software and as .pdf files to enable visualization in other computers, in which the Malvern software is not installed. Malvern software automatically and sequentially numbers every analysis; thus, deleting an analysis results in skipping a sequential number in the file. This serves as a protection against intentional and unintentional data deletion. All parameters of data generation (such as dilution, number of runs, type of sample) can be saved as notes in the data files.
- Viscosity data and raw absorbance from colorimetric methods (such as MTT, trypan blue and SRB assays) will be kept as Excel files. This type of file is easy for data export from equipment (such as plate readers) software, and readable in most computers. Data analysis will be performed in copies of the original file to preserve the integrity of raw data.
- Flow Cytometry data will be kept in FCS (Flow Cytometry Standard).
- Chromatograms will be kept as generated in the Shimadzu CLASS VP software. Information regarding the analysis (flow, wavelength, mobile phase) will be kept as .MET files, as generated by the Shimadzu CLASS VP software.
- Data from personal observations, batch number of reagents and drugs, information about concentrations, parameters used for data acquisition, and details on preparation of solutions and formulations will be kept in laboratory notebooks, which are not to be removed from the laboratory.
- Animal weight and other animal-related records will be kept in laboratory notebooks labeled with the protocol number and dates.